AUG 1 8 2006

3.2 Summary of Safety and Effectiveness K062247

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 as implemented in 21 C.F.R. §807.92.

The submitter of this premarket notification is:

Steve Singlar
Senior manager, Regulatory Submissions
Philips Ultrasound
MS 0135
3000 Minuteman Road
Andover, MA 01810
Tel: (978) 659-2101
Fax: (978) 975-7324

This summary was prepared on 28 June 2006

The proprietary name of the device is the HD11 Diagnostic Ultrasound System. In combination with the transducers listed in the Indications for Use tables are commonly known as a diagnostic ultrasound system and transducers.

These devices are classified as follows:

90IYN	Ultrasonic Pulsed Doppler Imaging System
90IYO	Ultrasonic Pulsed Echo Imaging System
90ITX	Diagnostic Ultrasound Transducer

As stated in 21 CFR, parts 892.1550, 892.1560 and 892.1570, each of these generic types of devices have been classified as Class II.

The HD11 is a diagnostic ultrasound device. It consists of a system console containing the power supply and electronic circuitry required to generate the image, a display screen and a connection to the separate transducers. It is substantially equivalent to other ultrasound systems including the Philips M2540A EnVisor and HDI-5000 series Ultrasound systems with transducers and EP MedSystems ViewMate® System with ViewFlex™ catheter VF-PA9F64ED.

The HD11 system and transducers function in a manner identical to all ultrasound systems and transducers. The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo-electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The differing acoustic properties of the tissues in the body reflect some of the transmitted energy back to the transducer, where it is converted back to electrical signals and sent back to the system. In the system, advanced signal processing technologies convert the returned signals into images of the tissues. The Doppler functions of this system process the Doppler shift frequencies from the echoes of moving targets (such as blood), to detect and graphically display the Doppler shifts of these tissues as flow.

The HD11 is intended for diagnostic ultrasound imaging and fluid flow analysis.

The HD11 is substantially equivalent in safety and effectiveness to the predicates identified above:

- Both the predicate device and the HD11 are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- Both the predicate device and the HD11 have the same gray-scale and Doppler capabilities.
- Both the predicate device and the HD11 use essentially the same technologies for imaging, Doppler functions and signal processing.
- Both the predicate device and the HD11 have acoustic output levels below the Track 3 FDA limits.
- Both the predicate device and the HD11 are manufactured under equivalent quality systems.
- Both the predicate device and the HD11 are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- Both the predicate device and HD11 are designed and manufactured to the same electrical and physical safety standards.

4.0 General Information

4.2 Basic Information

4.2.1 Manufacturer's Name

4.2.1.1 Manufacturer's Name (System and Transducers)

Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA. 98021

4.2.1.2 Manufacturer's Name (Catheter)

EP MedSystems
Cooper Run Executive Park
575 Route 73 North
Unit D
West Berlin, NJ 08091

4.2.2. Initial distributor

Philips Ultrasound

4.2.3 Device Name

HD11 Diagnostic Ultrasound System

4.2.4 Common Name

Diagnostic Ultrasound System and Transducers

4.2.5 Classification Name and Panel

Regulatory Class: II
Review Tier: II

Device Name	CFR Reference	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

4.6.2 Establishment registration Number

4.2.6.1 Philips Ultrasound Establishment Registration Number

3019216

4.2.6.2 EP MedSystems Establishment Registration Number

2248049

4.2.7 514 Performance Standards

There are no Sec. 514 performance standards for this device

4.2.8 Special Controls: 510(k) Special Report

The 510(k) Special Report, containing the final acoustic output, Doppler Sensitivity and labeling will be submitted prior to first customer shipment.

4.2.9 Prescription Status

This is a prescription device. The prescription device statement appears in the labeling.

4.2.10 Manufacturing Location

4.2.10.1 Philips Ultrasound Manufacturing Location

Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA. 98021

4.2.10.2 EP MedSystems Manufacturing Location

EP MedSystems
Cooper Run Executive Park
Unit D
575 Route 73 North
West Berlin, NJ 08091

4.2.11 Sterilization Site(s) (EP MedSystems Catheter ONLY)

North American Sterilization & Packaging Company
17 Park Drive
Franklin, NJ 07416

4.2.12 Reason for Submission

The contents of this submission describe an the addition of three renamed Philips ultrasound transducers:
C5-2 (K043535) renamed to C6-3, 3D6-2 (K043535) renamed to V6-2,
3D8-4 (K043535) renamed to V8-4
and the addition of the EP MedSystems ViewFlex™ catheter (K031066).

4.2.13 Track

This is a Track 3 system. The 510(k) Special Report will be submitted prior to domestic shipments of this device.

4.3 Indications for Use

4.3.1 Summary

The Philips HD11 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B, M, Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler (Color) and Amplitude Doppler (Angio), 3D, Harmonics, and combined mode (see table 4.3.2). It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Fetal
Abdominal
Pediatric
Intracrdiac
Intraoperative
Musculo-skeletal
Peripheral Vascular
Small Organ
Cardiac (Adult, Pediatric, Trans-esoph)
Endo-cavity (Trans-rectal, Trans-vaginal)
Adult and Neonatal Cephalic
Gynecological

(Please see the Indications for Use Summary page in section 4.3.2)

The clinical environments where the HD11 can be used include point-of-care areas in offices, clinical and hospital settings for screening and diagnosis of patients. These use models are within the scope of and substantially equivalent to current indications for use for ultrasound systems. See Table 4.4.1.4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2006

Philips Ultrasound
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K062247
Trade Name: HD11 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 1, 2006
Received: August 3, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the HD11 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C6-3 Curved Linear
V8-4 Curved Linear
V6-2 Curved Linear
ViewFlex™ Ultrasonic Catheter (Model# VF-PA9F64E2D)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

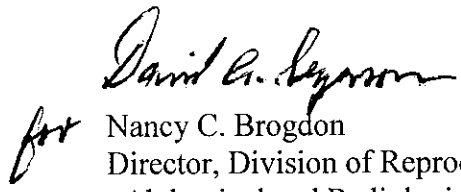
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, MD at (301) 594-1212.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

4.3.2 Indications for Use Tables

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: ~~K043535~~ K062247
System: Philips Ultrasound **HD11** Diagnostic Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	P		P	P	P	P	P
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Epicardial/Vascular)	P	P	P	P	P	P	P
	Intra-operative (Neuro)	P	P	P		P	P	P
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Thyroid, Scrotum, Breast)	P	P	P		P	P	P
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	P	P	P	P	P	P	P
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P
	Other (Fetal)	P	P	P		P	P	P
	Other (Intra-Cadriac)	N	N	N	N	N		
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (Carotid, I/O)	P	P	P		P	P	P
	Musculo-skel (conventional)	P	P	P		P	P	P
	Musculo-skel (superficial)	P	P	P		P	P	P

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D/4-D Imaging, Directional Angio Imaging, Tissue Doppler Imaging, 4D Fetal Heart, STIC (Spatial Temporal Image Correlation), SonoCT, X-Res, IMT Measures, iSCAN, 2D Doppler, Color Power Angio.

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual Mode,

Previous submission: **Cleared in K043535**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Lyerla

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062247 15

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K062247

System: Philips Ultrasound HD11 Diagnostic Ultrasound System

Transducer: C6-3 Curved Linear Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Scrotum, Thyroid, Breast)	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	P	P	P		P	P	P
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (Carotid)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: SonoCT, X-Res, Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, iSCAN, Doppler/2D, Color Power Angio

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Dual

Previous submission: **Cleared as C5-2 K014191, K043535**

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062247

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K062247

System: Philips Ultrasound HD11 Diagnostic Ultrasound System

Transducer: V8-4 Curved Linear Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Scrotum, Thyroid, Breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	P	P	P		P	P	P
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal Heart)	P	P	P		P	P	P
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: SonoCT, X-Res, Angio, Panoramic, Harmonics (Tissue), 3-D/4-D Imaging, Directional Angio Imaging, Fetal Heart (Spatial Temporal Image Correlation), Color Power Angio
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Real Time Biopsy, Dual
Previous submission: **Cleared as 3D8-4 on K043535**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K062247

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K062247

System: Philips Ultrasound HD11 Diagnostic Ultrasound System

Transducer: V6-2 Curved Linear Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Scrotum, Thyroid, Breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	P	P	P		P	P	P
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	P	P	P		P	P	P
	Other (Fetal Heart)	P	P	P		P	P	P
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes: SonoCT, X-Res, Angio, Panoramic, Harmonics (Tissue), 3-D/4-D Imaging, Directional Angio Imaging, Fetal Heart (Spatial Temporal Image Correlation), Color Power Angio

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color, Real Time Biopsy, Dual

Previous submission: **Cleared as 3D6-2 on K 043535, K034003**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Seyman

(Division Sign-Off)

Division of Reproductive, Abdominal,

Devices

K062247

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K062247

System: Philips Ultrasound HD11 Diagnostic Ultrasound System

Transducer: ViewFlex™ Ultrasound Catheter (Model# VF-PA9F64E2D)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph.							
	Other (Intra-cardiac)	**P**	**P**	**P**	**N**	**P**	**1, 2, 3**	
Peripheral Vessel	Peripheral vessel							
	Other							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes:
Combined modes: 1. B-Mode + M-Mode, 2. B-Mode + Pulsed Wave Doppler, 3. B-Mode + Color Doppler.
Previous submission: **Cleared in K031066**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K062247